REMARKS

Claims 1-16 are pending. Claims 14-16 have been withdrawn as being directed to a nonelected invention. Claim 3 has been cancelled. Claims 1, 2, 8, 10, 11, and 13 have been amended. Accordingly, claims 1-2 and 4-13 are under consideration.

Support for amendments to the claims is found in the original claims and throughout the specification. Specifically, support for the amendment to claim 1, which is directed to "a modified bacteriophage for use in the treatment or prophylaxis of a *Helicobacter pylori* infection " is supported by original claims 1 and 3. See also, for example, page 4, lines 19-23 of the specification wherein support for "genetically modified filamentous bacteriophages having a binding specificity for *Helicobacter pylori*" is presented; Examples 1-3 at page 9, line 7 to page 15, line 30, wherein guidance relating to production of monoclonal antibodies and recombinant M13 phage against *Helicobacter pylori*, and screening/testing thereof is presented; and Example 5, page 16, line 1 to page 17, line 12, wherein the effect of such modified filamentous bacteriophages on *Helicobacter pylori* growth is documented. Claim 2 has been amended to clarify the mucosal bacterial infection to which the claim is directed; support for the amendment to claim 2 is presented in original claims 2 and 3. Claims 8, 10, and 11 have been amended to clarify the language of the claims or correct a typographical error and support for these amendments is found in original claims 8, 10, and 11. Support for the amendment to claim 13 is offered at page 8, lines 5-12, wherein suitable means for administering a bacteriophage of the invention are found; at page 5, lines 13-20, wherein the recited purpose of the administering is presented; and in Example 5, page 16, line 1 to page 17, line 12, wherein the effect of a bacteriophage of the invention on *Helicobacter pylori* growth is documented. No issue of new matter is introduced by these amendments.

The Examiner refers to applicants' preliminary amendment filed 10-19-01. applicants' assume that the Examiner is referring to the preliminary amendment filed on August 10, 2001, wherein claims 4-8, 10, and 12-14 were amended. Applicants acknowledge that the amendments to these claims have been entered.

The Examiner has indicated that the Specification has been objected to because the Abstract of the disclosure should comprise proper language and be in an appropriate format. The Specification has also been objected to for the presence of an informality at page 29, line 1. In accordance with the Examiner's comments, the Specification has been

amended to correct these irregularities. No issue of new matter is introduced by these amendments.

The Examiner has indicated that although acknowledgment has been made of applicants' claim to foreign priority based on Swedish Application No. 9600434-6 (filed on 2-6-96), applicants are required to file a certified copy of this application. Accordingly, attached hereto is a certified copy of the Swedish Application No. 9600434-6.

In accordance with the Examiner's comments, the Specification has been amended to make specific reference U.S Application Serial No. 09/603,153, filed June 23, 2000, now U.S. Patent No. 6,497,874, which in turn claims priority from U.S. Application Serial No. 09/117,798, filed August 6, 1998, now abandoned, which was the national stage of International Application number PCT/SE97/00172, filed February 5, 1997, which claims priority from Swedish Application No. 9600434-6, filed February 6, 1996, to which the instant application claims priority. No issue of new matter is introduced by these amendments.

Claims 2 and 3 have been objected to as being of improper dependent form. Claim 3 has been cancelled, hereby obviating the objection to this claim. Applicants believe that the amendment to claim 2 addresses the issues raised and is, therefore, curative of the objection.

Rejections under the judicially created doctrine of obviousness-type double patenting

The Examiner has rejected claims 1-12 under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claim 1 of U.S. Patent No. 6,497,874. A Terminal Disclaimer is attached hereto, the filing of which is believed to overcome the above rejection of claims 1-12 under the judicially created doctrine of obviousness-type double patenting.

Rejections under 35 USC § 112

Claims 1-12 have been rejected under 35 USC § 112, second paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Claim 3 has been canceled, thereby obviating the

rejection of this claim. Claim 1 and dependent claims therefrom are allegedly vague for recitation of the term "modified bacteriophage". Claim 4 is allegedly vague for recitation of the phrase "modified filamentous bacteriophage"; claims 5 and 8 are allegedly vague for recitation of the phrase "modified M13 bacteriophage". Applicants respectfully disagree with the Examiner with regard to the absence of a definition for the term "modified" as it may pertain to aspects of the invention. At page 5, lines 13-23, for example, the specification presents a detailed description of what is meant by a "modified bacteriophage". In brief, a modified bacteriophage is a bacteriophage that presents at its surface a recombinant protein comprising a first component derived from a bacteriophage surface protein and a second component comprising variable region sequences of an antibody which provides a bacterial antigen binding site to the bacteriophage. Examples of the above "modified bacteriophage" are exemplified in "modified filamentous bacteriophage" and "modified M13 bacteriophage", support for which is found at page 5, lines 22-23. Additional support is provided in Example 2 (page 11, line 1 to page 14, line 11), wherein methods for producing recombinant or modified M13 phage are presented. Claim 11 has been amended to address issues pertaining to antecedent basis for terminology therein. Claim 13 has been amended to include essential steps.

In view of the above, applicants believe that the claims as presented herein are distinct and definite with regard to the subject matter to which they are directed. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1-12 under 35 USC § 112, second paragraph.

Claims 1-13 have been rejected under 35 USC § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one of skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 3 has been canceled, thereby rendering moot the rejection of this claim. Claim 1 and dependent claims therefrom have been amended to be drawn to a modified bacteriophage for use in the treatment or prophylaxis of a *Helicobacter pylori* infection comprising at its surface a recombinant protein which comprises a first component derived from a bacteriophage surface protein and a second component comprising variable region sequences of an antibody against *Helicobacter pylori* to provide a bacterial antigen binding site. The presence of the bacterial binding site confers on the bacteriophage

the ability to bind to *Helicobacter pylori*, and thus, inhibit the growth of these bacteria. Applicants assert that the specification provides detailed guidance with which a skilled artisan can make and use a bacteriophage for the treatment or prophylaxis of a *Helicobacter pylori* infection comprising at its surface a recombinant protein which comprises a first component derived from a bacteriophage surface protein and a second component comprising variable region sequences of an antibody against *Helicobacter pylori,* the presence of which provides a *Helicobacter pylori* antigen binding site. Such guidance is evident in the stepwise methodology presented in Examples 1-6 and Tables 1-3. See page 9, line 5 to 18, line 15 and pages 19-20. Additional guidance for identifying phages with desired properties is found at page 7, lines 7-29. Moreover, the specification teaches means for administration of a modified bacteriophage produced using the methods of the invention and suggests a dosage range for utilizing such a modified bacteriophage for the treatment or prophylaxis of a *Helicobacter pylori* infection. See page 8, lines 1-16.

In view of the clarification of the claims by amendment and ample teaching presented in the specification, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1-13 under 35 U.S.C. §112, first paragraph.

Rejections under 35 USC § 102

Claims 1-9 and 12 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by McCafferty et al., 1992 (WO 92/01047).

Claims 1-9 and 12 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by Winter et al., 1994 (Annual Review of Immunology 12:433-455).

Claim 3 has been cancelled, thereby mooting the rejection of this claim. Inasmuch as claims 1, 2, 4-9, and 12, as amended, are directed to methods of making and using modified bacteriophage that are engineered to recognize (i.e., bind) *Helicobacter pylori* by virtue of the incorporation of variable region sequences of an antibody against *Helicobacter pylori* into a recombinant surface protein of the modified bacteriophage, and there is no mention of this bacterial strain or variable region sequences of a *Helicobacter pylori* antibody in either McCafferty et al. or Winter et al., these references can not be properly interpreted to anticipate the present claims. Thus, applicants assert that these references are inappropriately cited with regard to the rejection of claims 1, 2, 4-9, and 12 under 35 U.S.C. §102(b). Accordingly, applicants respectfully request that the Examiner withdraw the rejection of claims 1, 2, 4-9, and 12 under 35 U.S.C. §102(b).

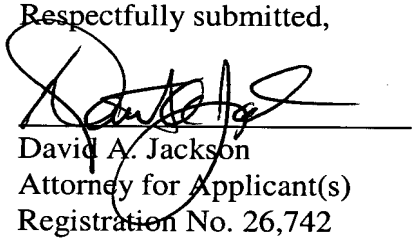
Fees

No additional fees are believed to be necessitated by this amendment. However, should this be an error, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment or to credit any overpayment.

Conclusion

It is submitted, therefore, that the claims are in condition for allowance. No new matter has been introduced. Allowance of all claims at an early date is solicited. In the event that there are any questions concerning this amendment, or application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of this application may be expedited.

Respectfully submitted,



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September 18, 2003

Attachments: Petition for Two-Month Extension of Time
Petition for Grant of Priority Under 35 USC 119
Certified Copy of the Swedish Application No. 9600434-6
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